K063507

NOV 3 0 2006

Section 9

510(k) - Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION

1. Device Name and Classification

Product Name:	***syngo Neuro PBV CT***
Classification Name:	Accessory to Computed Tomography System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	**Class II**
Product Code:	90 JAK

2. Importer/Distributor Establishment:
Registration Number: 2240869

Siemens Medical Solutions, Inc.
51 Valley Stream Pkwy
Malvern, PA 19355

FDA/CDRH/ODE/DMC
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3. Manufacturing Facility:

Siemens AG
Medical Solutions
Henkestrasse 127
D-91052 Erlangen, Germany

4. Contact Person:

Mr. Ralf Hofmann
Regulatory Submissions
Siemensstr.1; D-91301 Forchheim
Phone: +49 9191 18-8170
Fax: +49 9191 18-9782

5. Date of Preparation of Summary: October 23rd 2006

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

6. General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

7. Substantial Equivalence:

The syngo Neuro PBV CT software package, designed for post processing images that have been continuously acquired with computed tomography (CT) imaging systems which meet certain minimal requirements, is substantially equivalent to the following Siemens Medical Systems device:

Manufacturer	Product	510(k)	Clearance date
1. Siemens	NeuroDSA CT	K053024	11/04/2005
2. Siemens	Perfusion CT	K033832	12/23/2003
3. Siemens AG	Leonardo (syngo Fused Vision 3D)	K040970	07/08/2004

8. Device Description and Intended Use:

syngo Neuro PBV CT is a dedicated post-processing application used in cases of suspected stroke. The application calculates a volume that represents the amount of blood in the parenchyma. Decreased blood volume in a certain region of the brain is an indicator for stroke. As syngo Neuro PBV CT calculates a blood volume the stroke region can be measured in 3D.

Neuro PBV CT is calculated using a non-enhanced CT dataset (NECT) and a CT Angiography (CTA) that both are acquired during modern stroke protocol. The two volumes are first registered and after segmentation of bones, CSF, and vessels the volumes are low pass filtered and subtracted. The result is adjusted to the enhancement of a vessel to allow semi-quantitative measurements.

Syngo Neuro PBV CT helps to diagnosing stroke while enlarging the cerebral blood volume (CBV) of perfusion CT (PCT) that covers only a portion of the brain. Thus it facilitates the treatment decision and is an addition to Perfusion CT

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Stefan Preiss
Responsible Third Party Official
TÜV Product Service
1775 Old Hwy 8 NW, Ste 104
NEW BRIGHTON MN 55112-1891

NOV 30 2006

Re: K063507
Trade/Device Name: syngo Neuro PBV CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: November 16, 2006
Received: November 20, 2006

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 3

Indication for use

510(k) Number (if known): K061507

Device Name: ***syngo Neuro PBV CT***

syngo Neuro PBV CT is a dedicated post-processing application used in cases of suspected stroke. The application calculates a volume that represents the amount of blood in the parenchyma. Decreased blood volume in a certain region of the brain is an indicator for stroke. As syngo Neuro PBV CT calculates a blood volume the stroke region can be measured in 3D.

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Prescription Use ____X___ (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K063507